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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,752	01/16/2002	John D. Puskas	16294-0134 (45044-269130)	7521
23370	7590	09/30/2004	EXAMINER	
JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET ATLANTA, GA 30309			LAYNO, CARL HERNANDZ	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/051,752

Applicant(s)

PUSKAS, JOHN D.

Examiner

Carl H. Layno

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-102 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13-23, 25-36, 49-76 and 79-120 is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-11, 24, 37-40, 47 and 48 is/are rejected.
- 7) ☒ Claim(s) 5, 6, 12, 41-46, 51-57, 77 and 78 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for priority as a Division of U.S. Application Serial No. 09/716,783, filed November 20, 2000, now U.S. Patent No. 6,429,217, which is a Division of U.S. Application Serial No. 09/139,442, filed August 25, 1998, now U.S. Patent No. 6,479,523, which claims priority to U.S. Provisional Application Serial No. 60/072,284, filed January 23, 1998 and U.S. Provisional Application Serial No. 60/056994, filed August 26, 1997.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the details of the "apparatus for stimulating" including the "first electrode" and "second electrode" of claims 1, 13, 25, 37, 49, 61, 73, 85, 97, and 109 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must

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be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claims 51-57, 77, and 78 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 51-57, as written, repeats *verbatim* the contents of claims 3-9, respectively. To overcome this objection, the Examiner suggests changing the dependency of claims 51, 52, 53, and 55 to depend from claim 49 instead of from claim 1.

Claim 77, as currently written, depends upon itself. To overcome this objection, the Examiner suggests changing this claim to depend from independent claim 73.

Claim 78 is objected to since it depends from objected claim 77.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, in regard to claim 24, there is no antecedent basis for the term "said means for transmitting" (lines 1-2). To overcome this rejection, the Examiner recommends changing the dependency of the claim to depend from claim 23.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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7. Claims 1-4 and 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Wernicke et al '480.

The Wernicke et al '480 patent describes an electrical stimulus generator **10** (Fig. 1-3) for providing vagal nerve stimulation to treat eating disorders in a patient. The generator **10** is connected by wire leads **20** to electrodes **12-1, 12-2** (Fig. 2) secured within the patient's esophagus **14** (col. 8, lines 36-37). When activated, these would inherently cause the creation of an electric field.

In regard to claim 2, the electrodes **12-1** and **12-2** (Fig. 2) are located on opposite sides of the esophagus **14** (col. 8, lines 40-42), the diameter of which appears to be larger than one centimeter.

In regard to claim 3, control logic **25** (Fig. 1) is responsible for the actuation of the output section **36** which provides power to the electrodes **12-1** and **12-2**.

In regard to claim 4, the electrodes are bipolar or quadripolar (col. 8, lines 40-41).

In regard to claims 7 and 8, the Wernicke et al generator outputs pulses at a typical frequency range of between 5-150 Hz with a typical frequency being 25 Hz. See the Table of col. 13, line 65 thru col. 14, line 8.

In regard to claim 9, the Wernicke et al generator can produce stimulation pulses with frequencies of 40 Hz (col. 14, line 47) to treat small C fibers.

In regard to claim 10, the pulses generated by the Wernicke et al generator have a width of between 0.05-1.5 ms with a typical value of 0.5 ms.

In regard to claim 11, the Wernicke et al generator can produce a maximum output voltage of 14 volts (col. 12, line 6).

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8. Claims 37-40, 47, and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Loos '874.

The Loos '874 patent describes a method and stimulation apparatus (Fig.3) for manipulating the nervous system of a patient (Fig.1). The stimulation apparatus (Fig.3) includes a pair of surface mounted electrodes **2**, which may be placed on the patient's neck overlying the vagus nerve (col.25, lines 35-37). Timers **6** and **16** (Fig.3) perform the function of applicant's "means...for actuating" for activating the delivery of electric field **5** (Fig.2) to the patient.

In regard to claim 38, the electrodes **2, 2'** appear to be separated by approximately 1 cm. See Fig.10.

In regard to claim 40, the electrodes **2,2'** produce a bi-polar signal having both "positive and negative values" (col.7, lines 45-49).

In regard to claim 43, the apparatus of Loos produces pulses whose frequencies vary between 0.1 – 3 Hz (col.11, line 19), typically about 2-2.4 Hz.

In regard to claim 47, the output pulses have a maximum output voltage of 16 Volts peak-to-peak (col.9, lines 50-52).

In regard to claim 48, an output voltage of 2.4 volts peak-to-peak is used by the Loos device (col.9, lines 54-55).

Allowable Subject Matter

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9. Claim 24 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

10. Claims 5, 6, 12, and 41-46 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Claims 13-23, 25-36, 49-76, and 79-120 are allowed.

12. The following is a statement of reasons for the indication of allowable subject matter:

Applicant's claimed combinations of a vagus nerve stimulation device having a "first" and "second" electrode positioned within a patient's trachea and/or jugular vein could not be found in the prior art; consequently, the Examiner deems these claims to be allowable (i.e. independent claims 13, 25, 49, 61, 85, 97, and 109 and their depending claims).

The combination of one electrode in a patient's esophagus and a second electrode on a patient's neck was also found to be unique in the prior art. Unable to find any reference(s) showing this combination, the Examiner also deems claim 73 and its depending claims to be allowable.

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13. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a). **Corrected formal drawings** are now required.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The Wernicke et al '150 patent is cited for its pertinent vagal nerve stimulation capabilities and esophageal electrode placement.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (703) 308-3694. The examiner can normally be reached on Monday thru Thursday from 9 AM to 6 PM and every other Friday between 9AM and 5PM. A voice mail or E-mail message (carl.layno@uspto.gov) may be left if desired.

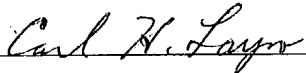
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes, can be reached on (703) 308-5181. All faxed correspondence should be sent to the Office's new Official FAX number (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Legal Instruments Examiner (LIE) Brenda Webb whose telephone number is (703) 305-7520.

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CARL LAYNO
PRIMARY EXAMINER

CHL

9/27/2004